NOTICE OF PROPOSED REGULATION AMENDMENTS

California Code of Regulations
Title 17. – Public Health
Division 4 - California Institute for Regenerative Medicine
Chapter 2. Medical and Ethical Accountability Standards
Amendments to Sections 100010-100050 & 100070

Date: July 15, 2016
Deadline for Submission of Written Comment: August 29, 2016 – 5:00 p.m.
Public Hearing Date: None Scheduled

Subject Matter of Proposed Amendments:
Loan Administration Policy

Sections Affected: The proposed regulatory action amends Chapter 2, Sections 100010 through 100050, and 100070, of Title 17 of the California Code of Regulations.

Authority: Article XXXV of the California Constitution and Health and Safety Code Section 125290.40, subdivision (j).

Reference: Sections 125290.30, Health and Safety Code.

Informative Digest/Policy Statement Overview:

The California Institute for Regenerative Medicine ("Institute" or "CIRM") was established in 2005 after the passage in 2004 of Proposition 71 (the "Act"), the California Stem Cell Research and Cures Initiative. The statewide ballot measure established a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities. The Independent Citizens' Oversight Committee ("ICOC") is the 29-member governing board for the Institute. The ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry. The Act charges the ICOC with developing standards and criteria to make grant awards and to develop standards and criteria for proper oversight of awards. (§ 125290.50.) To that end, CIRM has adopted rules regarding Intellectual Property and specifically a regulation governing publications of CIRM-funded research.

The Scientific and Medical Accountability Standards Working Group ("Standards Working Group" or "SWG") makes recommendations to the ICOC on scientific, medical and ethical standards pertaining to stem cell research the Institute funds. Specifically, California Health and Safety Code section 125290.55 requires the Standards Working Group to: 1) recommend to the ICOC scientific, medical and ethical standards; 2) recommend to the ICOC standards for all medical, socioeconomic, and financial aspects of clinical trials and therapy delivery to patients, including, among others, standards for safe and ethical procedures for obtaining materials and cells for research and clinical efforts for the appropriate treatment of human subjects in medical research consistent with paragraph (2) of subdivision (b) of Section 125290.35, and to ensure compliance with patient privacy laws; 3) recommend to the ICOC

modification of the standards described in numbers (1) and (2) as needed; 4) make recommendations to the ICOC on the oversight of funded research to ensure compliance with the standards described in numbers (1) and (2); and, 5) advise the ICOC, the Scientific and Medical Research Funding Working Group, and the Scientific and Medical Research Facilities Working Group on an on-going basis on relevant ethical and regulatory issues.

The Scientific and Medical Accountability Standards ("MES") Working Group convened to consider new amendments to the MES regulations. One of the primary goals of these amendments is to align the MES regulations with CIRM 2.0 and associated revisions to the Grants Administration Policy already approved by the ICOC. Thus, the proposed amendments are designed to provide agency-wide alignment of operations, procedures and policies.

A series of amendments were considered at a public meeting of the CIRM Scientific and Medical Accountability Standards Working Group in April 2015. The proposed amendments are grouped into three categories.

Anticipated Benefits and Purposes of Proposed Amendments:

(1) Amendments intended to align MES Regulations with CIRM 2.0 & GAP revisions
These amendments primarily involve incorporating terms such as "grantee" that are in the revised GAP. In addition, the term "human subjects research" is defined to align the MES regulations with Federal policies for protection of research subjects.

(2) Amendments intended to make the regulations clearer and easier to implement
These amendments primarily involve section 100050 Compliance and 100085 Fetal Tissue. Section 100050 contains provisions identical to those in CIRM's Grants Administration Policy. Rather that restate the requirements here, CIRM proposes referring to the applicable section of the GAP. Section 100085 reiterates Federal policy regarding use of fetal tissue in research. CIRM proposes referencing the applicable Federal policy requirement.

(3) Amendments to regulatory review and oversight
Two policy changes relating to animal studies are proposed. The first change to section 100030 would allow the breeding of animals where covered stem cell lines have been introduced provided human genetic material does not contributed to the germ line. This policy is consistent with the 2010 National Academies' Guidelines for Human Embryonic Stem Cell Research and is designed to allow multigenerational safety studies of stem cell therapies in animal models.

The second change proposes to exempt pre-clinical animal studies, where human neural progenitor cells are transplanted to the brains of mature animals, from review by a stem cell research oversight committee provided the study is being performed pursuant to an FDA IND or IDE. The rationale for this change is twofold. First, institutional animal care and use committees (IACUCs) provide oversight for animal studies. Second, a major goal of the CIRM 2.0's Late Stage Preclinical Projects is to speed the introduction of therapies into the clinic. Organizations applying under CIRM 2.0 may not have access to a stem cell research oversight committee thus creating a potential barrier to entry.

Consistency with Existing State Regulations:
After performing an evaluation for any other regulations in this area, CIRM has determined that these are the only regulations dealing with recipients of CIRM funds, and therefore the proposed regulations are neither inconsistent nor incompatible with existing state regulations.

DISCLOSURES REGARDING THE PROPOSED AMENDMENTS:
CIRM has made the following initial determinations:

Mandate on local agencies and school districts: CIRM has determined that the proposed amendments do not impose a mandate on local agencies or school districts, nor do they require reimbursement by the state pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code because the amendments do not constitute a "new program or higher level of service of an existing program" within the meaning of Section 6 of Article XIII of the California Constitution.

Submittal of Comments:

Any interested party may present comments in writing about the proposed amendments to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on August 29, 2016. Comments regarding this proposed action may also be transmitted via e-mail to mescomments@cirm.ca.gov.

Public Hearing:
At this time, no public hearing has been scheduled concerning the proposed regulations. If any interested person or the person's representative requests a public hearing, he or she must do so in writing no later than August 15, 2016.

Effect on Small Business:
CIRM has determined that the proposed amendments will have no impact on small businesses. The regulation implement medical and ethical standards for CIRM-funded stem cell research. This research is conducted almost exclusively by large public and private nonprofit institutions. As such, the amendments to the regulation are not expected to adversely impact small business as defined in Government Code Section 11342.610.

Impact on Local Agencies or School Districts:

CIRM has determined that there are no costs to any local agency or school district that are required to be reimbursed pursuant to Government Code section 17500 et seq.

Other Nondiscretionary Cost or Savings to Local Agencies

CIRM has also determined that there are no other nondiscretionary cost or savings imposed upon local agencies that will result from the proposed amendments.

Costs or Savings to State Agencies:
CIRM has determined that no savings or increased costs to any agency will result from the proposed amendments.

Effect on Federal Funding to the State:
CIRM has determined that no costs or savings in federal funding to the state will result from the proposed amendments.

Effect on Housing Costs:
CIRM has determined that the proposed amendments will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:
CIRM has made an initial determination that the proposed amendments will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California Businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses:
CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed amendments.

Results of Economic Impact Analysis:

Under section 3 of the "California Stem Cell Research and Cures Act," which established the California Institute for Regenerative Medicine, funds for this agency are continuously appropriated without regard to fiscal year and not subject to budgetary control. The Act requires CIRM adopt rules to apply to Grants and Loans made by the agency.

CIRM has determined that that proposed regulatory action has no direct impact on small businesses. Virtually all applicants for CIRM funding are either large academic nonprofit institutions or well-capitalized biotechnology ventures. As such, the regulation is not expected to adversely impact small business as defined in Government Code section 11343.610. Application for grant funds is voluntary and grant awards are required by Proposition 71 to include a prescribed additional amount to cover any costs associated with administration of the grant by grant recipients.

This action is not expected to have a direct impact on the creation or elimination of jobs, nor the creation of new businesses or elimination of existing businesses, nor the expansion of business currently doing business within the State of California because the regulation affects only administrative requirements regarding use of loan and grant funds. The use of CIRM funds is required neither by law nor these regulations. To the extent the amendments facilitate use of the funds and encourage development of intellectual property and return to the state as required by law, and to the extent California institutions apply for and receive research funds, such requirements are indirectly attributable to increased economic activity spurred by the investment research funds in the state and resultant positive business and employment development. Also, to the extent the amendments make it possible for the expenditure of research funds in the state, and to the extent that research results in medical treatments and cures for chronic disease and injury, the regulation indirectly benefit the health and welfare of California residents who will benefit from such treatments and cures.

Consideration of Alternatives:
In accordance with Government Code Section 11346.5, subdivision (a)(13), CIRM must determine that no reasonable alternative it considered, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of the law than the proposal described in this Notice. CIRM invites interested persons to present statements or arguments with respect to alternatives to the proposed amendments at the scheduled hearing or during the written comment period.

Availability of Statement of Reasons and Text of Proposed Regulations:
CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed amendments, all of the information upon which the amendments are based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text:
After considering all timely and relevant comments, CIRM may adopt the proposed amendments substantially as described in this notice. If CIRM makes modifications that are sufficiently related to the originally proposed text of the amendments, it will make the modified text (with the changes clearly indicated) available to the pubic for at least 15 days before it adopts the regulations as amended. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Agency Contact:
Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the amendments; and inquiries regarding the rulemaking file may be directed to:

Scott Tocher
Deputy General Counsel
California Institute for Regenerative Medicine
1999 Harrison Street, Suite 1650
Oakland, CA 94612
(415) 396-9100

Questions on the substance of the proposed regulatory action may be directed to:

Amy Cheung
California Institute for Regenerative Medicine
(415) 396-9100

The Notice of Proposed Regulatory Amendment, the Initial Statement of Reasons and any attachments, and the proposed text of the amendments and existing regulation are also available on CIRM's website, www.cirm.ca.gov.

Availability of Final Statement of Reasons:
Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code Section 11346.9, subdivision (a), may be obtained from the contact person named above.

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